UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, Plaintiff, vs. BARR LABORATORIES, INC, Defendant.	))))))))	1:02-CV-1844-SEB-VSS

ORDER GRANTING LIMITED EXTENSION OF STATUTORY STAY

Plaintiff, Eli Lilly and Company ("Lilly"), seeks to extend the statutory thirty-month stay based on Defendant's, Barr Laboratories, Inc. ("Barr"), alleged failure to produce a sample of its proposed drug product which Barr intends to sell and is the subject of its ANDA, claiming that until Barr identifies and produces such a sample of its proposed drug product, Lilly cannot conduct necessary discovery and trial cannot commence. Indeed, Lilly notes, the "anchor date" in the revised Case Management Plan controlling all the other relevant deadlines in this case is the date upon which Barr can describe and provide a sample of its raloxifene product. Lilly also maintains that this delay by Barr has prevented it from obtaining evidence needed to resolve the infringement issues in this case and that Barr thus has "failed to reasonably cooperate in expediting the action...". 21 U.S.C. § 355(j)(5)(B)(iii).

Barr opposes Lilly's requested extension of the statutory stay on the grounds that such relief is extraordinary and rarely granted, and the request is not premised on any

showing that Barr has failed to reasonably cooperate in expediting this action, and in any event, any entitlement to a stay is not contingent upon the admittedly incomplete FDA-approval process. In fact, Barr maintains that, rather than itself, Lilly has been the foot-dragger and obstructionist in bringing this case to trial readiness and should not now be permitted to benefit from its own dilatoriness.

Who has been the foot-dragger and who has not is difficult for the Court to determine in the context of a single motion, but it does appear important, perhaps essential, that the composition of the generic drug product for which FDA approval is being sought by Barr and which Lilly alleges to be the infringing product should be definitively established. Therefore, in order to resolve the immediate issue, the Court hereby extends the statutory stay, but only until such time as Barr has produced a sample of its proposed drug product and identified its nature and composition as it plans to sell it and makes that information known to Lilly, after which time the stay shall continue only through a reasonably expeditious time period for preparing for trial. When Barr certifies to the Court that it has made the referenced disclosure to Lilly, the stay shall be lifted, subject, as we have said, only to an additional time period that is reasonable and necessary to complete discovery and bring the case to trial. How long the stay is in effect is thus largely within the control of Barr; the sooner it produces the product, the sooner the matter will be tried and the sooner the stay will be lifted. IT IS SO ORDERED.

Date: 05/27/2005

SARAH EVANS BARKER, JUDGE
United States District Court
Southern District of Indiana

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Attorneys of record